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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,786	11/08/2001	Simon Robitaille	3648.028	2013

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EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/005,786	ROBITAILLE ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 723 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 08 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/04/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This general action is in response to the application filing date of 11/08/2001

Claim Objections

1. Claims 1 and 3 are objected to because of the following informalities:

In claim 1, line 10, applicant recites, "to a sterilization chamber lowering". A connecting phrase is needed to show that the sterilization pressure results in lowering the boiling point of water. Appropriate correction is required.

In claim 3, line 1, applicant recites, "when operated at". Removal of "when" is needed to provide a clear meaning for claim 3. Appropriate correction is required.

2. Claims 5-6 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 5. See MPEP § 608.01(n). Accordingly, the claims 5-6 have not been further treated on the merits.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1-4, 7-13 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carman et al (U.S.P.N. 6,284,193) in view of Joslyn (U.S.P.N. 4,770,851).

With respect to claims 1 and 12, the Carman reference teaches a method and an apparatus (col.1, lines 9-12) using ozone-containing gas (col.2, lines 25-30) to sterilize medical articles including the following: providing a sterilization chamber (1), placing articles in the chamber (col.7, lines 29-30), sealing the chamber (col.7, lines 30-31), applying vacuum to the chamber (col.7, lines 53-56 and 5) such that the range of the Carman vacuum (upon conversion from pounds per inch square to millbar) as disclosed by the specification (paragraphs 00018 and 00019 and paragraph 00030) intrinsically results in lowering the boiling point of water in the sterilization chamber to a temperature below the temperature in the chamber, supplying water to humidify the atmosphere within the chamber (col.7, lines 56-58 and 12), supplying ozone-containing gas to the

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chamber (col.7, lines 59-64 and 6), maintaining the vacuum in the chamber over the treatment time interval (col.7, lines 64-667 and col.8, line 1) and releasing the vacuum in the chamber (col.8, lines 2-3). However, with respect to claims 1 and 12, the Carman reference fails to disclose equalizing the temperature of the articles and the chamber atmosphere. The Joslyn reference, which is in the art of gas sterilization of medical articles, teaches (figure 2, 103 through 107, col.4, lines 26-29, 38 and 33) repeatedly applying vacuum and then injecting heated air as needed (equivalent to the equalization step). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of the Carman reference by adding an equalization step as taught by the Joslyn reference in order to insure that the humidified sterilant reaches the interstices of medical articles (col.1, lines 14-17).

With respect to claim 2, the Joslyn reference teaches the step of equalizing (figure 2, 103 through 107, col.4, lines 26-29, 38 and 3).

With respect to claims 3-4, 7-8, 11, 13 and 15-22 the Carman reference teaches the following: chamber temperature of 25 degree Celsius (col.7, lines 24-25 such that 80 degrees Fahrenheit is equal to 27 degree Celsius), humidity level of 98 % (col.4, lines 16-19), means for destroying ozone (9), vacuum within the chamber is maintained for a preselected time interval (col.7, lines 64-67 and col.8, line 1) such that the vacuum (col.7, lines 54-55) is adjusted to any desired value within the disclosed range (col.7, lines 54-56), an ozone generator (6), a pump (5) that generates vacuum range that includes 55.3 mbar and higher (col.7, line 55), an intrinsic means for controlling the

concentration of ozone in order to maintain such a concentration (col.4, lines 36-41) and adjusting the vacuum pressure (col.7, lines 42-44 including a value for maintaining vacuum).

With respect to claims 9-10, the Carman reference fails to teach the concept of repeating steps; however, the Joslyn reference teaches repeating air removal steps (col.4, lines 26-29) and aeration steps (col.6, lines 25-32) as many times as necessary in order to obtain desired results such as insuring that the humidified sterilant reaches the interstices of medical articles. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Carman reference by repeating any step or steps in the process of sterilizing medical articles so that certain objectives are achieved, for example, insuring that the humidified sterilant reaches the interstices of medical articles (col.1, lines 14-17).

With respect to claim 23, the Carman reference teaches that all parameters of the sterilization process are controlled by a programmable industrial process controller (8). This teaching intrinsically includes feedback mechanisms, for example, based on readings from ozone level and vacuum pressure values within the chamber (col.4, lines 36-39 and col.7, lines 52-56).

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carman et al (U.S.P.N. 6,284,193) in view of Joslyn (U.S.P.N. 4,770,851) and further in view of Faddis et al (U.S.P.N. 5,344,622).

With respect to claim 14, both the Carman reference and the Joslyn reference teach the following: a chamber door (For example, 14 in the Joslyn reference), a

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humidifier (both references provide humidity from an intrinsic source), means for controlling the chamber temperature (both references use chamber heating means), means for controlling the door (both references seal the chamber) and means for controlling the humidifier (both references must intrinsically include some humidity control means in order to introduce and stop the introduction of humidity into the chamber);however, both fail to teach the use of a water reservoir. The Faddis reference, which is in the art of ozone sterilization, teaches using a water reservoir as a source for humidity. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the Carman reference by substituting one source of humidity for another as evidenced by the Carman reference (84 and col.8, lines 25-28).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Shapiro reference (3,719,017) teaches the concept of repeating steps in an ozone sterilization process. The Patapoff et al reference (U.S.P.N. 5,656,246) teaches sterilizing articles by using humidified ozone and the Green reference (U.S.P.N. 5,702,669) teaches applying heat to chamber door.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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01/31/2005

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